

Meeting Minutes
April 20, 2018
1:00 p.m. - 4:00 p.m.
Iowa Medicaid Enterprise conference rooms 128 & 130

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1.	<ul> <li>Welcome and Introductions</li> <li>A. Announcements - C. David Smith, MD, General Surgery, IME Medical Director, opened the meeting with a welcome and introductions were made.</li> <li>Present: Nicholas Galioto, MD, Family Practice;</li> <li>Daniel Wright, DO, Pediatrics; Dennis Zachary, MD, Family Practice; Andrea Silvers, MD, Family Practice; Sherry Buske, ARNP, Family Practice;</li> <li>Kathleen Lange, MD, Family Practice;</li> <li>Mark Randleman, DO, IME Physician Reviewer;</li> <li>Mark Dearden, DO, United Healthcare; and Angela Kloepfer, MD, Amerigroup.</li> <li>Absent: KellyAnn Light-McGroary, MD, United Healthcare; and Mark Levy, MD, Amerigroup.</li> <li>B. Non-committee members present: Lisa Borland, Joshua Selsby, Amy Aikens, Jennifer Shumsky,</li> </ul>	Dr. Smith
	Tami Sova, Dr. Seth Perlman, Christina Trout,	
	Rick Riley, Tanya McAninch, Vicki Lickteig,	
	Paula Motsinger, Colleen Kacher, Cassie Reece,	
	and Jane Riggins.	
2.	Approval of Minutes from the January 19, 2018 Meeting	Dr. Smith
	A. Motion to approve by - Nicholas Galioto	
	Seconded by - Sherry Buske	
3.	Minutes were unanimously approved. Old Business	
ა.	A. State Innovation Model (SIM) Update	Tanya McAninch
	Tanya stated the Healthcare Innovation and	
	Visioning Roundtable meet every other month and	
	met in February and April. This roundtable was	
	developed to foster engagement of important	
	leaders around the state to develop consensus and	
	transform how the healthcare system operates to	
	best serve the needs of all lowans. Through this	
	meeting, A Healthy Communities and A Data Use	
	and Sharing workgroup will be formed. Each workgroup will include at least one appointed	
	member of the roundtable and 8-11 volunteers who	
	will meet over the next several months to develop	
	and guide recommendations for the governor's	
	office with the goal of building an improved and	
	sustainable healthcare system.	
	The SIM team is awaiting formal approval from	
	CMMI on the SIM operational plan for Award Year 4.	



	This award year will be focused on achieving the identified goals that are both impactful and sustainable for the healthcare landscape in Iowa. SWAN/IHIN – The IHIN is in the early stages of the process of onboarding providers to the new Orion HE Platform. Several provider organizations are in the testing phase while others are just beginning. The expansion of SWAN continues. The IHIN is piloting new alerting software - CMT - with three C3 communities in Webster, Sioux and Muscatine counties. Participating organizations within the C3 community will be boarded to the new Orion Platform and will submit and receive alerts through the enhanced system. The new system uses realtime clinical data to populate.  Social Determinants of Health (SDOH) - the standardized SDOH questions have been integrated into Assess My Health. They cover social topics to identify disparities of Housing Security, Healthcare Confidence, Employment Status, Basic Human Needs Security (Food, Clothing, etc.), Personal and Community Safety, and overall Stress Level. The modified tool has begun to collect relevant SDOH data in our C3 communities by the Healthiest State Initiative and through Annual HRAs that are	
	reviewed at least quarterly and will be combined	
	with other data to begin to establish a connection	
	between SDOH and value-based care.	
4.	New Business	Dr. Dearden
٦.	A. MCO Medical Directors Update -	Dr. Kloepfer
	Dr. Dearden from UHC stated their leadership has	Dr. Riocpiei
	been traveling the state and meeting with case	
	managers in communities to build relationships. They	
	experienced a large expansion in December and	
	focused on reinforcing skills and training and	
	provider education.	
	Dr. Kloepfer from Amerigroup stated they met the	
	state fiscal goal for children and that provider	
	disputes are decreasing. She also stated the media	
	coverage has been highlighting cases for contract	
	rates.	
	Dr. Smith stated IME has a new Medicaid Director -	
	Michael Randol, as well as a new DHS Director -	
	Jerry Foxhoven. IME is looking at the fiscal impact of policies and a cost benefit ratio that is reasonable.	
	policies and a cost benefit fatio that is reasonable.	



	He stated there have been 1,600 appeals within the last year and that 49 of those were reversed. IME continues to work on a better alignment of decisions with regard to the Iowa Administrative Code (IAC). Dr. Randleman posed the question - why does the ALJ not take medical information into account when making their judgements? Dr. Smith stated there is a DME workgroup and their focus is on the IAC and wheelchairs. They are looking at a base rate, the CMS guidelines, and what Medicaid will cover and what the facility will cover. He stated they will be looking at oxygen and incontinence supplies next.	
	B. Recommendations for new members on CAC - Dr. Smith stated he is asking Seth Perlman, MD, a pediatric neurologist from Iowa City, to join the CAC. He will continue to take recommendations for new CAC members. Dr. Smith reiterated the availability of CAC meetings to be attended telephonically and that anyone is allowed to call in for the meetings; however, public comments may only be made in-person.	Dr. Smith
5.	<ul> <li>Public Comment Period –</li> <li>A. Tami Sova: For Nusinersen, she asked the CAC to reconsider the age of three weeks old for treatment. Most patients who receive this medication do not survive past two years of age. They have difficulty swallowing, feeding, and with respiratory function. Of patients that were pre-symptomatic, 100 percent remained alive and free of permanent ventilation if they received this medication. She stated that Type 0 (inutero) is rare and has not been tested.</li> <li>B. Joshua Selsby: For Eteplirsen, he spoke on Criterion #3 with the requirement of members achieving an average distance of 180 meters in 6 minutes. He stated that measuring ambulation is just one of the many milestones that impact quality of life and that this excludes other areas of skeletal muscles such as deltoids and biceps. He stated there is also a variability in patient response. He asked the CAC that the criteria be system-wide and not zero in on ambulation. He asked why the range of 3-14 years of age for the 6 minute walk test as earlier treatment can produce results. He recommends treatment as soon as the diagnosis is made. He asked about the continuation of treatment after 6 months and the decline of 20 percent - what is the baseline and how is it measured?</li> </ul>	Dr. Smith



- He asked about the renewal of treatment every six months being based on clinical parameters - what are the clinical parameters? He asked why it was necessary to document progressive disease despite standard corticosteroid therapy?
- C. Lisa Borland: For Eteplirsen, she addressed questions about younger patients in clinical studies, stating that there is a safety study in patients between 4 and 6 years of age and a safety study that is evaluating younger patients between 6 months to 48 months. She stated that the label is unrestricted by age or ambulatory status. She summarized recent pulmonary function analyses in both ambulatory and non-ambulatory DMD patients, which showed a slower rate of pulmonary function decline in Eteplirsen-treated patients compared to natural history. In response to questions about monitoring parameters, she stated that the 6MWT is not consistently performed in clinical practice. She also communicated that the prescribing information was revised in February to include information about hypersensitivity reactions.
- D. Jennifer Shumsky: For Eteplirsen, she is the parent of a Duchenne muscular dystrophy child. She advocates for safe and effective treatment. She stated the disease affects all muscles and not just those used for ambulation. She stated the criteria give the appearance that once the patient is able to be sitting, no other improvements are needed.
- E. Amy Aikens: For Eteplirsen, she is the parent of a Duchenne muscular dystrophy child. She asked that no specific age, muscles, or distance be mentioned in the criteria. Her child was not able to meet the 6-minute walk test. She stated that the medication is not a cure; however, it delays the progression of the disease.
- F. Christina Trout/Seth Perlman, MD: Dr. Perlman spoke on Eteplirsen and stated many clinics do not have a dedicated space to perform the 6-minute walk test. He stated there are other motor impacts beyond ambulation, such as upper extremity function. He spoke on meaningful motor skills such as the ability to feed yourself with the use of your arms. He stated that patients with the disease have respiratory muscle function decrease by four percent per year and with the medication the decrease is two percent per year. He spoke on the age limitations and asked why 14 years of age was the upper age limit?



	He spoke on Nusinersen and said that testing	
	involves two physical therapists at \$300 each to	
	monitor the motor functioning. After loading doses of	
	the medication are given, a new set of physical	
	therapy assessments are conducted which requires	
	an additional appointment. Their office needs a full-	
	time person to handle the prior authorizations for this	
	medication.	
	He stated it is difficult to receive an approval for each	
	one due to the frequency. He asked if monthly is	
	needed or could we go to every six months? If you	
	could have six months to get the first loading doses	
6	in and then could it go to annually?	Dr. Cmith
6.	Criteria Review	Dr. Smith
	Blepharoplasty – Added narrative under Criteria.	
	Added c and d under Criterion #1. Added CPT Codes	
	for Brow Ptosis, Canthoplasty, and Conjunctivo-tarso-	
	Muller's muscle-levator resection.	
	Rhinoplasty - Combined criteria for Septoplasty/	
	Rhinoplasty.	
	<ol><li>Septoplasty - Combined criteria for Septoplasty/</li></ol>	
	Rhinoplasty.	
	4. Vagus Nerve Stimulator - Deleted Criteria #2 and #3.	
	Added new Criterion #2. Added picture diagram.	
	Added References Used.	
	<ol><li>Varicose Vein Treatment - No changes</li></ol>	
	recommended.	
	<ol><li>CDAC WPA - Added Criterion #12.</li></ol>	
	7. Gait Trainer - Combined criteria for Gait Trainer and	
	Standing Frame System to be Gait Trainer/Stander.	
	8. Negative Pressure Wound Therapy - Added Criterion	
	#5, #6 and #7.	
	9. Non-Elastic Compression Devices - Added f and g	
	under Criterion #1. Added to Criterion #7 "with	
	member on a mineralcorticoid".	
	10. Personal Care Services for Children - No changes	
	recommended.	
	11. Private Duty Nursing for Children - No changes	
	recommended.	
	12. Safety Beds - Added second paragraph regarding	
	IAC.	
	13. Shower/Commode Chair - No changes	
	recommended.	
	14. Standing Frame System - Combined criteria for Gait	
	Trainer and Standing Frame System to be Gait	
	Trainer and Standing Frame System to be Gait Trainer/Stander.	
	15. Skilled Level of Care - No changes recommended.	
	16. Eteplirsen (Exondys 51) - Review at July CAC.	



	17. Nusinersen (Spinraza) - Review at July CAC.		
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	18. Vitamin, Mineral, Amino Acid Supplements -		
	Re-worded Criterion #1.		
	19. Genetic Testing – Criterion #1 added "or phenotype"		
	and "defined". Criterion #2 deleted "and/or to rule out		
	or rule in a diagnosis". Under Fragile X added		
	narrative on specific codes for high risk pregnancies.		
	CAC went into a closed session and asked the visitors to		
	leave in order to discuss Eteplirsen and Nusinersen. After		
	discussion, the CAC recommendation is to make no		
	decisions regarding changes on these two criteria and to		
	review them again at the July CAC meeting. CAC members		
	asked for the current criteria and the proposed changes to		
	be sent to them for review before the next meeting.		
7.	Other New Business/Discussion	C	ommittee
	There was no new business.		
8.	Upcoming Meetings	Dı	r. Smith
	A. July 20, 2018		
	B. October 19, 2018		
9.	Adjournment of Meeting	Dı	r. Smith
	Motion to adjourn - Kathleen Lange		
	Seconded - Andrea Silvers.		

#### Contact:

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